



BILLING CODE 4150-36

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0260]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments to Sherette.Funn@hhs.gov or by calling (202) 795-7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-New-60D and project title for reference., to Sherette.funn@hhs.gov, or call the Reports Clearance Officer..

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2)

the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: 0990-0260-Extension Protection of Human

Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB

Recordkeeping/Informed Consent/Consent Documentation.

Abstract: Assistant secretary for Health, Office for Human Research Protections is requesting an extension on a currently approved information collection by the Office of Management and Budget, on the Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation. The purpose of the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) is to provide a uniform government-wide standard for institutions engaged in research conducted or supported by the Department of Health and Human Services (HHS) to apply regarding the protection of human subjects involved in research. The HHS codification of the Common Rule is at 45 CFR part 46 subpart A. The respondents for this collection are institutions engaged in such research. Institutional adherence to the Common Rule also is required by other federal departments and agencies that have codified or follow the Common Rule which is identical to 45 CFR part 46, subpart A.

Likely Respondents: Institutions engaged in nonexempt human subject's research.

ESTIMATE ANNUALIZED BURDEN IN HOURS TABLE

Title	Number of Respondents	Number of responses per respondent	Average burden per response (in hours)	Total Burden hours
.103(b)(4), .109(d) IRB Actions, .116 and .117 Informed Consent	6,000	39.33	1	235,980
.115(a) IRB Recordkeeping	6,000	15	10	900,000
.103(b)(5) Incident Reporting, .113 Suspension or Termination Reporting	6,000	0.5	45/60	2,250
Total				1,138,230

Terry S. Clark,

Asst Information Collection Clearance Officer.

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